

REMARKS

Continued prosecution and consideration of the claimed subject matter in the accompanying patent application is respectfully requested.

Claims 34, 39, 52 and 53 have been amended. Claims 42-45 and 47-51 are withdrawn. Claims 28-32, 34, 39, 52 and 53 were noted to be objected to as depending from a rejected claim. Claims 26-34, 36-41, 46 and 52-57 are in the case and are before the Examiner.

I. The Amendments

Each of claims 34, 39, 52 and 53 has been amended to cancel the word "vaccine" and replace it with the phrase "immunogenic composition". These amendments complete the amendments carried out in the previous amendment that inadvertently did not include the present amendments. These amendments add no new matter.

II. The Action

A. Rejection Under 35 USC §112, Second Paragraph

Claims 34, 39, 52 and 53 were rejected under the Second Paragraph of Section 112 as being indefinite. The basis for this rejection was the continued inclusion of the word "vaccine". It is believed that the present amendments have made this basis for rejection moot.

B. Rejection Under 35 USC §102

Claims 26, 27, 36, 37, 38, 40, 41, 46, and 54-56 were rejected under Section 102 as allegedly being anticipated by the

disclosures of Kurtz et al. US Patent No. 5,691,189, hereinafter Kurtz. The gist of this rejection is that Kurtz expresses the M2 protein in yeast cells and those cells constitute a heterologous presenting carrier. This basis for rejection cannot be agreed with and is respectfully traversed.

It is first noted that the claims require a "fusion product" that is comprised of at least two parts. It is submitted that the phrase "fusion product" has a well-known meaning in the art that indicates that the recited parts are chemically linked together.

A search of the US PTO data base of issued patents was conducted by the undersigned seeking presumptively valid US patents that used the phrase "fusion product" in the claims. The search noted 111 such patents. (A copy listing the most recently issued 50 such patents is enclosed as Exhibit A.) It is thus submitted that there is an art-based recognition and understanding of that phrase.

It is submitted that the Kurtz disclosure contains no such disclosure of the expressed protein being linked to a carrier as a fusion product. Rather, the Action asserts that the yeast cells are themselves the carrier, and that that carrier along with the membrane-inserted M2 protein constitute the claimed subject matter. It is submitted that construct does not meet the claim limitations and this basis for rejection should be withdrawn.

It is further submitted that the recited presenting carrier "potentiates the immunogenicity of the fusion product" (PCT publication, p. 6, l. 25-26; US 2006024092 Paragraph 0058). This is not so in Kurtz. In particular, the full-length M2 protein is inserted in Kurtz into the plasma membrane of the yeast cells. However, because the yeast cells also possess a

cell wall external to the plasma membrane, it is evident that the M2 protein and its extracellular part are not directly exposed, *i.e.*, *presented*, to the immune system by the cells, but are instead concealed beyond the barrier formed by the cell wall.

Consequently, in the particular arrangement employed by Kurtz, the yeast cells cannot be considered a heterologous presenting carrier according to the claimed invention because the cells do not improve the presentation of the extracellular part of M2 to the immune system, and thus do not potentiate the immunogenicity of the extracellular M2 part. It is again submitted that this basis for rejection should be withdrawn.

C. Rejection Under 35 USC §103

Claims 26, 27, 36, 37, 38, 40, 41, 46 and 54-57 were rejected as allegedly obvious over the disclosures of Kurtz, as above, in view of Sunstrom et al., *J. Membrane Biol.* 1996 **150**:127-132, hereinafter "Sunstrom". The gist of this argument is that the NB protein of influenza forms ion channels as does the M2 protein, so it would be obvious to substitute the NB protein for the M2 protein of Kurtz. This basis for rejection cannot be agreed with and is respectfully traversed.

It is respectfully submitted that this basis for rejection is inapt for at least the last-stated reason that the Kurtz teaching did not anticipate the claimed subject matter. Thus, in this instance, the yeast cells cannot be considered a heterologous presenting carrier according to the claimed invention because the cells do not improve the presentation of the NB protein to the immune system, and thus do not potentiate the immunogenicity of the NB protein. Still further, , Kurtz also does not motivate to improve the presentation of the NB

protein by its yeast cells, because it contains no teaching nor suggestion that any immune response could at all be generated by its yeast cells. Thus, this basis for rejection should also be withdrawn.

III. Summary

Claims 34, 39, 52 and 53 have been amended. Each basis for rejection has been overcome or otherwise made moot.

It is therefore believed that this application is in condition for allowance of all of the pending claims. An early notice to that effect is earnestly solicited.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution. It is noted that the undersigned is a new counsel for this application. A formal Power of Attorney is enclosed herewith.

Respectfully submitted,

By 
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Attachments

Exhibit A
Power of Attorney with statement
Extension of Time Fee